MEMORANDUM

DATE: October 13, 2000

SUBJECT: ID# 036501 Addendum to the Acute Dietary Exposure Analysis for Coumaphos.

DP Barcode: D267978 Class: Acaricide
Chemical#: 036501

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HED has revised the last acute dietary exposure analysis (D262058, S. Mason, 1/13/2000) in the process of confirming previous work in preparation for a forthcoming Section 18 action for coumaphos in honey. This revision includes only a correction to the aforementioned 1/13/2000 acute dietary exposure analysis; the residue data file (rdf) for milk was used for milk and also inadvertently for pork fat. The rdf file for pork fat was not used in the original analysis. The correction was made and the acute dietary exposure recalculated. No other changes were made to the original 1/13/2000 acute dietary analysis (see the previously cited memo for any further information). The corrected Dietary Exposure Evaluation Model (DEEM) acute input file and the corrected analysis file are attached.

Executive Summary

The original analysis used refined acute dietary exposure assessments for the organophosphorus insecticide coumaphos to determine the risks associated with uses of coumaphos for the control of arthropod pests on cattle, horses, and swine. Anticipated residues (ARs) were utilized to estimate exposure to coumaphos in the diets of the U.S. population, as well as certain sub-populations. Refinements to percent livestock treated (%LT) information are incorporated into the assessment.

Acute risks associated with the use of coumaphos do not exceed HED's level of concern (>100% PAD[1]). The estimated acute dietary risk is 21% of the acute PAD at the 99.9th percentile for the most highly exposed sub-population, infants <1 year of age.

Toxicological Information

On May 11, 1999, the Hazard Identification Assessment Review Committee (HIARC) met to discuss acute and chronic hazard endpoint selection for dietary exposure to coumaphos. The HIARC recommended to the FQPA Safety Factor Committee that the FQPA factor be removed in assessing the risk posed by coumaphos (N. Paquette memo, 5/12/99). In a meeting on May 17, 1999, the FQPA Safety Factor Committee accepted this recommendation, and the FQPA safety factor was removed (B. Tarplee memo, 06/01/99). Since the FQPA safety factor was reduced to 1X, the acute and chronic PADs are equivalent to their respective RfDs.

The toxicology database for coumaphos is complete, and will support reregistration. Coumaphos is a Group E chemical, indicating that it is not likely to be carcinogenic in humans via relevant routes of exposure.

The following toxicology endpoints are used in the acute and chronic dietary risk assessment:

Table 1: Doses and Endpoints Selected for Acute and Chronic Dietary Risk Assessment

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT
Acute Dietary	**LOAEL= 2.0 UF = 300 100X inter-and intraspecies extrapolation and 3X lack of NOAEL**	**Plasma ChE inhibition in females and RBC ChE Inhibition in both male and female rats**
	Acute RfD = 0.007 mg/kg/day aPAD = 0.007 mg/kg/day	
Chronic Dietary	**NOAEL=0.025 UF = 100 100X inter-and intraspecies extrapolation**	**Plasma and RBC ChE Inhibition in both male and female dogs**
		Chronic RfD = 0.0003 mg/kg/day
	Chronic RfD = 0.0003 mg/kg/day cPAD = 0.0003 mg/kg/day	

ChEI = Cholinesterase Inhibition.

[1] PAD = Population Adjusted Dose = $\frac{\text{Acute or Chronic RfD}}{\text{FQPA Safety Factor}}$

Residue Information

The published tolerances for coumaphos are listed in 40 CFR §180.189. Tolerances are listed for:

Meat, fat, and meat byproducts of cattle, goats, hogs, horses, poultry and sheep 1.0 ppm
Milk-fat residues, reflecting negligible residues in milk 0.5 ppm
Eggs 0.1 ppm

No changes to the milk, cattle, horse, and hog tolerances were required for the original analysis. Although tolerances are still listed for poultry, eggs, goats, and sheep, the use of coumaphos on poultry and eggs has been canceled and the use of coumaphos on goat and sheep will be revoked. The acute DEEM analysis used the following anticipated residue values, calculated in a memo by M. Metzger, dated 7/18/89, with the exception of milk. The residue values used for milk are from the United States Department of Agriculture's (USDA's) Pesticide Data Program (PDP) 1997 and 1998 monitoring data which show no detectable residues in milk out of 750 samples tested. The residue data studies for coumaphos continue to be acceptable. The AR values calculated in the M. Metzger memo are still considered appropriate for dietary risk assessment purposes; however, all ARs should be re-evaluated in five years. The chronic AR for beef fat has been revised to 0.072 ppm from 0.15 ppm (C. Olinger memo, 3/7/95).

Table 2: Anticipated Residue Values for Use in Calculating Acute and Chronic Exposure

Commodity	%LT	Anticipated Residue (ppm)	
		Acute	
Beef (and horse), lean meat without removable fat	5% beef only	RDF, 0.05	95 ZEROS 5 @ 0.05
Beef, fat	5%	RDF, 0.40	95 ZEROS 5 @ 0.40
Beef, liver (and meat by-products)	5%	RDF, 0.10	95 ZEROS 5 @ 0.10
Beef, kidney	5%	RDF, 0.04	95 ZEROS 5 @ 0.04
Hog, lean meat	1%	RDF, 0.20	99 ZEROS 1 @ 0.20
Hog, fat	1%	RDF, 0.60	99 ZEROS 1 @ 0.60
Hog, liver (and meat by-products)	1%	RDF, 0.02	99 ZEROS 1 @ 0.02
Hog, kidney	1%	RDF, 0.02	99 ZEROS 1 @ 0.02
Veal, lean meat without removable fat	100%	0.05	NA

Commodity	%LT	Anticipated Residue (ppm)	
		Acute	
Veal, fat	100%	0.40	NA
Veal, liver (and meat by-products)	100%	0.10	NA
Veal, kidney	100%	0.04	NA
Milk	4%	RDF,0.016	720 ZEROS 30 @ 0.016

Note: Residue Data File (RDF).
The chronic milk anticipated residue incorporates the %LT.

Refinements using percent livestock treated information have been incorporated into the dietary exposure analysis for acute risk. The DEEM default concentration factors were used in the acute analysis. Additional processing data (i.e. cooking and processing studies) would help to further refine the risk.

Essentially all beef consumed in the United States is cooked prior to consumption. An open literature study entitled "Effect of pH and Cooking Temperature on the Stability of Organophosphate Pesticides in Beef Muscle" (J. Agric. Food Chem. 1994, vol. 42, pages 2035-2039) shows that coumaphos decomposes under thermal conditions. Since nearly all meat products are cooked typically at temperatures similar to or higher (and often for longer durations) than those used in this study, it seems likely that reduction of acute dietary exposure to coumaphos would occur from cooking beef before consumption (S. DeVito memorandum dated 23/Nov./98).

Results and Discussion

The Tier 3 acute dietary exposure assessments was performed using DEEM. DEEM is used to estimate exposure to constituents in foods comprising the diets of the U.S. population, including population subgroups. The software contains food consumption data from the U.S. Department of Agriculture Continuing Survey of Food Intake by Individuals (CFSII) from 1989-1992. A summary of the residue information used in the acute analysis is attached (Attachments 1).

Acute Exposure Analysis: (Tier 3)

The refined acute dietary risk analysis estimates the distribution of single day exposures for the overall U.S. population and certain subgroups and evaluates exposure to coumaphos for each food commodity. The calculated acute exposure (residue x consumption) was compared to an aPAD of 0.007 mg/kg/day, which reflects an FQPA factor of 1x. The results of the acute dietary analysis are attached (Attachment 2).

Table 3: Acute Dietary Risk Estimates

Population	(95th Percentile)		(99th Percentile)		(99.9th Percentile)	
	Exposure mg/kg/day	**% aPAD**	**Exposure mg/kg/day**	**% aPAD**	**Exposure mg/kg/day**	**% aPAD**
U.S. Population	0.000018	<1%	0.000147	2%	0.000525	8%
All Infants (<1 year)	0.000028	<1%	0.000161	2%	**0.001492**	**21%**
Children 1-6 years	0.000065	<1%	0.000488	7%	0.001070	15%
Children 7-12 years	0.000034	<1%	0.000267	4%	0.000521	7%
Females 13-50 years	0.000010	<1%	0.000101	1%	0.000247	4%

Conclusions

At the 99.9th percentile, the acute dietary risk estimates associated with the use of coumaphos do not exceed the HED's level of concern for any population subgroup. The acute dietary risk estimate for the highest exposed sub-population (infants <1 year) at the 99.9th percentile is 21% of the aPAD.

Attachments

Attachment 1: Residue Information (Acute)
Attachment 2: Results of Acute Dietary Exposure Analysis
Attachment 3: RDF files

cc: S. Mason, RAB2 RF, L. Richardson

Attachment 1

Filename: C:\coumapho\036501nh.RS7 Chemical: Coumaphos
RfD(Chronic): .00025 mg/kg bw/day NOEL(Chronic): 0 mg/kg bw/day
RfD(Acute): .007 mg/kg bw/day NOEL(Acute): 0 mg/kg bw/day
Date created/last modified: 06-15-2000/09:16:12/8 Program ver. 7.075

RDL indices and parameters for Monte Carlo Analysis:

Index #	Dist Code	Parameter #1	Param #2	Param #3
1	6	BeefFat.rdf		
2	6	BeefKdny.rdf		
3	6	BeefLean.rdf		
4	6	BeefLivr.rdf		
5	6	milk.rdf		
6	6	milk.rdf		
7	6	PorkFat.rdf		
8	6	PorkLean.rdf		
9	6	PorkLivr.rdf		
10	6	honey.rdf		

Food Code	Crop Grp	Food Name	Def Res (ppm)	Adj.Factors #1	#2	RDL Pntr
318	D	Milk-nonfat solids	0.020000	1.000	1.000	5
319	D	Milk-fat solids	0.020000	1.000	1.000	5
320	D	Milk sugar (lactose)	0.020000	1.000	1.000	5
321	M	Beef-meat byproducts	0.100000	0.050	1.000	4
322	M	Beef-other organ meats	0.100000	0.050	1.000	4
323	M	Beef-dried	0.050000	0.096	1.000	3
324	M	Beef-fat w/o bones	0.400000	0.050	1.000	1
325	M	Beef-kidney	0.040000	0.050	1.000	2
326	M	Beef-liver	0.100000	0.050	1.000	4
327	M	Beef-lean (fat/free) w/o bones	0.050000	0.050	1.000	3
334	M	Horsemeat	0.050000	1.000	1.000	
342	M	Pork-meat byproducts	0.020000	0.010	1.000	9
343	M	Pork-other organ meats	0.020000	0.010	1.000	9
344	M	Pork-fat w/o bone	0.600000	1.000	1.000	7
345	M	Pork-kidney	0.020000	0.010	1.000	9
346	M	Pork-liver	0.020000	0.010	1.000	9
347	M	Pork-lean (fat free) w/o bone	0.200000	0.010	1.000	8
398	D	Milk-based water	0.020000	1.000	1.000	5
424	M	Veal-fat w/o bones	0.400000	1.000	1.000	
425	M	Veal-lean (fat free) w/o bones	0.050000	1.000	1.000	
426	M	Veal-kidney	0.040000	1.000	1.000	
427	M	Veal-liver	0.100000	1.000	1.000	
428	M	Veal-other organ meats	0.100000	1.000	1.000	
429	M	Veal-dried	0.050000	1.920	1.000	
430	M	Veal-meat byproducts	0.100000	1.000	1.000	

Attachment 2

U.S. Environmental Protection Agency Ver. 7.075
DEEM ACUTE analysis for COUMAPHOS (1989-92 data)
Residue file: 036501NH.RS7 Adjustment factor #2 NOT used.
Analysis Date: 06-23-2000/15:08:44 Residue file dated: 06-23-2000/11:35:07/8
Daily totals for food and foodform consumption used.
MC iterations = 5000 MC list in residue file MC seed = 1
Run Comment: " For 5000 iterations"
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Summary calculations (per capita):

	95th Percentile		99th Percentile		99.9th Percentile	
	Exposure	% aRfD	Exposure	% aRfD	Exposure	% aRfD
U.S. Population:	0.000018	0.25	0.000147	2.10	0.000525	7.50
All infants:	0.000028	0.40	0.000161	2.30	0.001492	21.32
Nursing infants (<1 yr old):	0.000000	0.00	0.000036	0.51	0.000313	4.47
Non-nursing infants (<1 yr old):	0.000045	0.65	0.000186	2.66	0.001578	22.55
Children 1-6 yrs:	0.000065	0.93	0.000488	6.97	0.001070	15.28
Children 7-12 yrs:	0.000034	0.49	0.000267	3.82	0.000521	7.44
Females 13+ (preg/not nursing):	0.000014	0.20	0.000143	2.04	0.000281	4.02
Females 13+ (nursing):	0.000015	0.22	0.000117	1.67	0.000281	4.02
Females 13-19 (not preg or nursing):	0.000014	0.20	0.000139	1.99	0.000312	4.45
Females 20+ (not preg or nursing):	0.000009	0.13	0.000091	1.30	0.000235	3.35
Females 13-50 yrs:	0.000010	0.14	0.000101	1.45	0.000247	3.53
Males 13-19 yrs:	0.000019	0.27	0.000162	2.31	0.000346	4.94
Males 20+ yrs:	0.000012	0.16	0.000098	1.40	0.000272	3.89

Attachment 3
RDF files:

Pork
Byproducts, Kidney, Liver, Other organs
TOTALZ=99
TOTALNZ=1
0.02

Pork
Lean
TOTALZ=99
TOTALNZ=1
0.2

Pork
Fat
TOTALZ=99
TOTALNZ=1
0.6

Milk
TOTALNZ=1
TOTALZ=720
TOTALLOD=29
LODRES=0.016
0.016

Beef Cattle
Byproducts, liver, other organ
TOTALZ=95
TOTALNZ=5
0.1
0.1
0.1
0.1
0.1

Beef Cattle
Lean, dried
TOTALZ=95
TOTALNZ=5
0.05
0.05
0.05
0.05
0.05

Beef Cattle
Fat
TOTALZ=95
TOTALNZ=5
0.4
0.4
0.4
0.4
0.4

Beef Cattle
Kidney
TOTALZ=95
TOTALNZ=5
0.04
0.04
0.04
0.04
0.04